

Attorney Docket No.: 6200.200-US
USSN: 09/921,429
Express Mail Label No.: EV 409530602 US

Remarks

Applicants respectfully note that it is well-settled in order to combine features from the prior art references, the prior art must provide a motivation for such a combination and the mere fact that a worker of ordinary skill could rearrange the parts of a reference is not sufficient to support obviousness. See Ex Parte Chicago Rawhide 223 USPQ 351 (Bd Pat App. & Inter. 1984).

It is also well-settled that if a reference or the prior art in general teaches away from the claimed invention, then such teaching supports a finding of non-obviousness, or conversely a finding of patentability of the claimed invention. In the previous Office Actions, the Examiner rejected the pending claims in view of Nguyen et al and Current under 35 USC 103 and argued repeatedly through out prosecution of this case that the motivation to combine references would come from a desire to limit overall size. Assuming, without conceding, that one would be motivated to reduce the size of a needle magazine, one would be motivated to avoid the claimed invention because, as is discussed below and recognized by European patent authorities, applicants' design is one of the least efficient in terms of needles storage per unit volume. Thus, the Examiner's reasoning clearly supports that the prior art teaches away from the claimed invention.

Furthermore, Nguyen et al -- the primary reference -- explicitly teaches that the magazine should be as small as possible to accommodate being carried by a user. (See Nguyen et al at Col 2, line 61). Therefore, the references when taken together would discourage one from arriving at applicants' claimed invention. Indeed, since the claimed invention is volumetrically one of the least efficient designs in which to store needles, without applicants disclosed inventive

contribution, no one would be motivated to design applicants' claimed invention. Of course, applicants' own disclosure cannot be a basis for an obviousness rejection.

The following will clearly demonstrate that applicants' invention goes against the explicit teaching of the prior art and the Examiner's assertions that one of ordinary skill would know that a magazine should be as small as possible. In fact, as is demonstrated below, the claimed invention results in a larger magazine than other configurations and thus contradict's conventional wisdom. As such it is non-obvious.

As is shown in the figures below, a cylindrical magazine with radial cavities to hold 14 standard injection pen needles in sterile sleeves requires a minimum diameter of 8.5 cm.

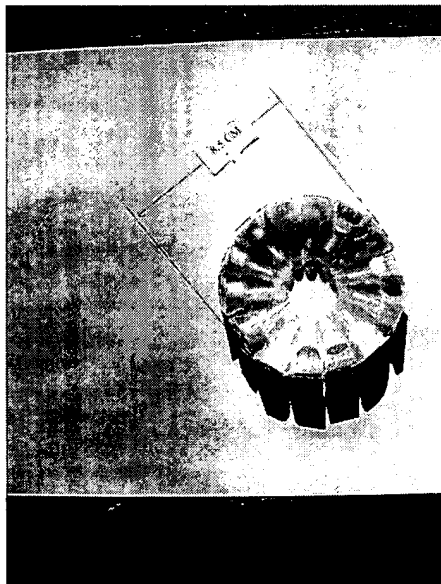


Figure 1

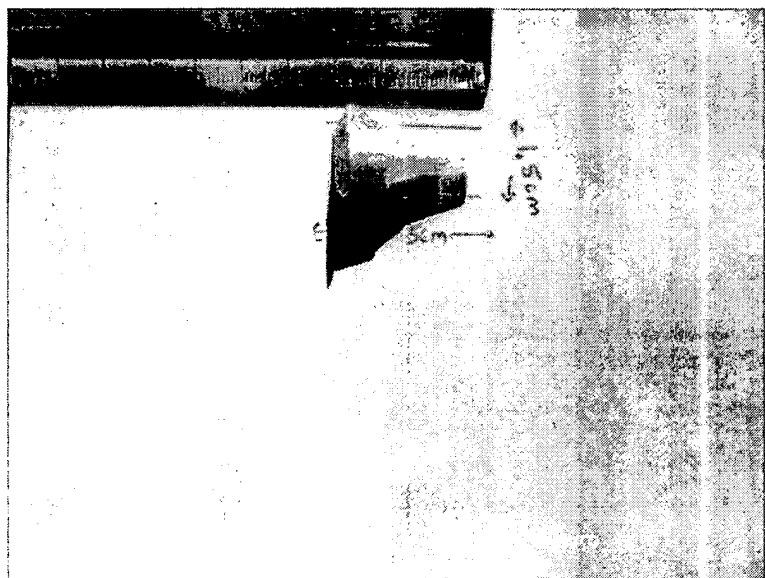


Figure 2

Assuming the height would be only slightly greater than the diameter of the needles at their hub, which is about 1.5 cm, the magazine as a total volume of $(8.5/2)^2 * 3.14159 = 85.1 \text{ cm}^3$. On a per needle assembly basis, this means that one needle assembly is stored per 6.07 cm^3 of space.

Assuming (as the Examiner does and as is suggested by the primary reference the Examiner cites against applicants invention) that one would design a magazine to reduce space, one would select a rectangular configuration (as is shown above) or some other configuration besides a cylindrical one with radial cavities and a sterility barrier.

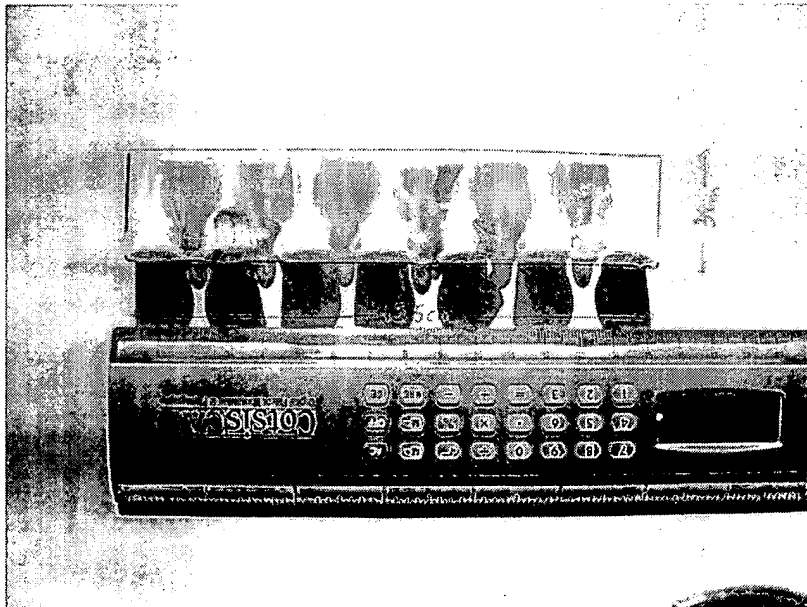


Figure 3

If one skilled in the art were to follow the teachings of the prior art, as well as or in addition to the Examiner's suggested motivation, to make the magazine as small as possible, other configurations – and not the claimed configuration—would natural flow from such motivation.

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One such configuration that would natural flow would be a rectangular configuration as is shown

in Figure 3 above. Here the same 14 needles fit into a rectangular magazine having a length of 15.5 cm, a height of 1.5cm (slightly larger than the diameter of the needles at their hubs) and a width of 3 cm. As a result 14 needles fit in a much smaller space, approximately 69.57 cm^3 .

This results in one needle being stored in 4.97 cm^3 of space. Thus, one following the Examiner's motivation, as well as the explicit teaching of the prior art, would avoid a cylindrical magazine with radial cavities.

It is exactly this reasoning that the European patent office relied upon in issuing a preliminary examination report showing that applicants' invention is patentable. The report, which is attached hereto, in discussing the radial orientation of the cavities states in pertinent part, "[t]here is no reason to make the vertical cavities 31 for needles 100 in D3 (Nguyen et al) horizontal because it will make the diameter of the wheel larger (length of needles) and D3 (Nguyen et al) column 2 line 61 says the container 30 should be convenient to carry for the patient. If the diameter is made larger the container 30 is more difficult to carry in a pocket." The above figures demonstrate clearly and unambiguously that this is true.

Thus, not only does the claimed invention go against the explicit teaching of the prior art reference, but also the only motivation to combine the features of a cylindrical magazine with radial cavities in the two disparate, cited patents, would be applicants discovery of a new and useful tool for mounting needles to a pen injector. As previously discussed, applicants

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discovered that their alignment of the cavities makes the magazine useful as a tool in mounting

needles to an injection pen. Neither of the patents cited by the Examiner, taken alone or in

combination teaches a tool for attaching a needle to an injection device wherein the tool is

rotated 360 and the injection device is rotated 360 and neither alone, or in combination suggests

that such a tool would provide increased leverage. The references when read together do not

teach that it would be desirable to develop a wrench or tool that assist in mounting pen needles

on injection devices or that such tool could also serve as a magazine. In fact, the references

suggest limiting size and as discussed above, if one were to limit size then one would pick a

different configuration. Thus, the only motivation to combine the features of the references (so

that a resulting magazine has radial cavities and can accommodate hub mounted needles while

preserving sterility) is the unexpected result that the applicant's have found that changing the

orientation of the cavity results in increased leverage. Of course, such hindsight reconstruction is

not permissible during examination.

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Conclusion

In view of the above, Applicants respectfully submit that all claims are in condition for allowance and the typographical errors in the specification have been addressed. Reconsideration of the pending application is kindly requested. The Commissioner is hereby authorized to charge any fees in connection with this application, including any fees for extensions of time, and to credit any overpayments to Deposit Account No. 14-1447.

The Examiner should feel free to contact the Applicants attorney by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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